►**B**

COMMISSION DIRECTIVE 2003/68/EC

of 11 July 2003

amending Council Directive 91/414/EEC to include trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole as active substances

(Text with EEA relevance)

(OJ L 177, 16.7.2003, p. 12)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Directive 2004/65/EC of 26 April 2004	L 125	43	28.4.2004

▼B

COMMISSION DIRECTIVE 2003/68/EC

of 11 July 2003

amending Council Directive 91/414/EEC to include trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole as active substances

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market [1], as last amended by Commission Directive 2003/39/EC [2], and in particular Article 6(1) thereof,

Whereas:

(1) In accordance with Article 6(2) of Directive 91/414/EEC the United Kingdom received on 28 January 1998 an application from Novartis Crop Protection UK Ltd for the inclusion of the active substance trifloxystrobin in Annex I to Directive 91/414/EEC. The substance was subsequently transferred to Bayer CropScience, which is now acting as the applicant. Commission Decision 1999/43/EC [3] confirmed that the dossier was 'complete' in the sense that it could be considered as satisfying, in principle, the data and information requirements of Annexes II and III to Directive 91/414/EEC.

(2) France received an application under Article 6(2) of Directive 91/414/EEC on 14 February 1996 from FMC Europe NV (now FMC Chemical sprl) concerning carfentrazone-ethyl. This application was declared complete by Commission Decision 97/362/EC [4].

(3) The United Kingdom received an application under Article 6(2) of Directive 91/414/EEC on 23 April 1998 from Zeneca Agrochemicals UK (now Syngenta) concerning mesotrione. This application was declared complete by Commission Decision 1999/392/EC [5].

(4) France received an application under Article 6(2) of Directive 91/414/EEC on 15 September 1999 from Rhone Poulenc Agri SA (now Bayer CropScience) concerning fenamidone. This application was declared complete by Commission Decision 2000/251/EC [6].

(5) The Netherlands received an application under Article 6(2) of Directive 91/414/EEC on 6 March 1996 Rhône-Poulenc Agro (now Bayer CropScience) concerning isoxaflutole. This application was declared complete by Commission Decision 96/524/EC [7].

(6) For those active substances, the effects on human health and the environment have been assessed, in accordance with the provisions of Article 6(2) and (4) of Directive 91/414/EEC, for the uses proposed by the applicants. The nominated rapporteur Member States, submitted a draft assessment report concerning the substance to the Commission on 19 April 2000 (trifloxystrobin), 14 May 1998 (carfentrazone-ethyl), 17 December 1999 (mesotrione), 14 May 1998 (fenamidone) and 20 February 1997 (isoxaflutole).

---

[1] OJ L 230, 19.8.1991, p. 1.
[2] OJ L 124, 20.5.2003, p. 30.
[3] OJ L 14, 19.1.1999, p. 30.
[4] OJ L 152, 11.6.1999, p. 31.
[5] OJ L 148, 15.6.1999, p. 44.
[6] OJ L 78, 29.3.2000, p. 26.
[7] OJ L 220, 30.8.1996, p. 27.

▼B

(7) The draft assessment reports have been reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health. The review was finalised on 15 April 2003 in the format of the Commission review reports for mesotrione, trifloxystrobin, carfentrazone-ethyl, fenamidone and isoxaflutole.

(8) The review of trifloxystrobin and fenamidone did not reveal any open questions or concerns, which would have required a consultation of the Scientific Committee for Plants.

(9) For carfentrazone-ethyl the review and information were also submitted to the Scientific Committee for Plants for separate consultation. The Committee was asked to comment on the relevance for humans of the elevated levels of specific porphyrins detected in test animals. The Committee expressed the opinion ([1]) that the effects of the substance detected in test animals on porphyrin levels are relevant for humans but saw no evidence that humans are more sensitive to the effect than animals. In addition, the Scientific Committee noted that three unknown polar compounds were detected in a lysimeter. The notifier was therefore requested to comment on the relevance of these three compounds. Additional information was subsequently provided by the notifier and evaluated by the Committee. In its assessment of the new data the Committee concluded that those polar compounds will not cause an unacceptable ecotoxicological or toxicological risk.

(10) For mesotrione, the Scientific Committee was asked to comment on the suitability of the rat as an animal model for the extrapolation of the toxicological properties of mesotrione in humans and was invited to assess, whether the onset of adverse effects in target organs (in animal models as well as humans) can be linked to a certain threshold concentration of tyrosine in plasma. In its opinion ([2]), the Committee concluded that due to the similarities in tyrosine kinetics between mice and humans, the mouse can be considered a better animal model than the rat for human risk assessment purposes. The Committee further concluded that no signs or symptoms of adverse effects are to be expected in humans at plasma tyrosine levels below 800 to 1 000 nmol/ml.

(11) For isoxaflutole the Scientific Committee was asked to comment on the toxicological and ecotoxicological effects of a degradation product of the active substance (RPA 203328); on statistical analyses of tumour incidence in the two-year rat study; and on the observation of developmental effects in laboratory animals. In its opinion ([3]), the Committee noted that the degradation product RPA 203328 under worst-case conditions might leach into groundwater with expected concentrations exceeding 0,1 ppb. The Committee identified no toxicological or ecotoxicological concern with regard to this degradation product. The Committee also identified no concern for humans related to possible carcinogenic or developmental effects.

In a second consultation on the same substances the Scientific Committee was asked to comment on the appropriate degradation kinetics to be assumed in model calculations of the leaching behaviour. The Committee found certain parameters

([1]) Opinion of the Scientific Committee for Plants regarding the evaluation of carfentrazone-ethyl in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/CARFEN/002-final adopted 26 January 2001.

([2]) Opinion of the Scientific Committee for Plants on the evaluation of mesotrione in the context of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/MESOTRI/002-final of 18 July 2002.

([3]) Opinion of the Scientific Committee for Plants regarding the inclusion of isoxaflutole in Annex 1 of Directive 91/414/EEC concerning the placing of plant protection products on the market. SCP/ISOXA/012-final of 3 June 1999.

▼B

used in the modelling were insufficiently justified and the half life time of degradation for the RPA 203328 metabolite may have been under-estimated ([1]).

The model calculations of the leaching behaviour of isoxaflutole and its degradation products were subsequently revised along the lines suggested by the Scientific Committee.

(12) It has appeared from the various examinations made that plant protection products containing the active substances concerned may be expected to satisfy, in general, the requirements laid down in Article 5(1)(a) and (b) and Article 5(3) of Directive 91/414/EEC, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to include mesotrione, trifloxystrobin, carfentrazone-ethyl, fenamidone and isoxaflutole in Annex I, in order to ensure that in all Member States the authorisations of plant protection products containing these active substance can be granted in accordance with the provisions of that Directive.

(13) After inclusion, Member States should be allowed a reasonable period to implement the provisions of Directive 91/414/EEC as regards plant protection products containing trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone and isoxaflutole and in particular to review existing provisional authorisations and, by the end of this period at the latest, to transform those authorisations into full authorisations, to amend them or to withdraw them in accordance with the provisions of Directive 91/414/EEC.

(14) It is therefore appropriate to amend Directive 91/414/EEC accordingly.

(15) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 91/414/EEC is amended as set out in the Annex to this Directive.

Article 2

Member States shall adopt and publish by 31 March 2004 at the latest the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof.

They shall apply those provisions from 1 April 2004.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

1. Member States shall review the authorisation for each plant protection product containing trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone or isoxaflutole to ensure that the conditions relating to these active substances set out in Annex I to Directive 91/414/EEC are complied with. Where necessary, they shall amend or

([1]) Opinion of the Scientific Committee for Plants on additional questions from the Commission concerning the evaluation of isoxaflutole in the context of Directive 91/414/EEC. SCP/ISOXAFLUTOLE-bis-002 final of 30 January 2003.

▼B

withdraw authorisations in accordance with Directive 91/414/EEC by 31 March 2004 at the latest.

▼M1

2. For each authorised plant protection product containing trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone or isoxaflutole as either the only active substance or as one of several active substances, all of which were listed in Annex I to Directive 91/414/EEC, by 30 September 2003 at the latest, Member States shall re-evaluate the product in accordance with the uniform principles provided for in Annex VI to Directive 91/414/EEC, on the basis of a dossier satisfying the requirements of Annex III to that Directive. On the basis of that evaluation, they shall determine whether the product satisfies the conditions set out in Article 4(1)(b), (c), (d) and (e) of Directive 91/414/EEC.

Following that determination Member States shall:

(a) in the case of a product containing trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone or isoxaflutole as the only active substance, where necessary, amend or withdraw the authorisation by 31 March 2005 at the latest; or

(b) in the case of a product containing trifloxystrobin, carfentrazone-ethyl, mesotrione, fenamidone or isoxaflutole as one of several active substances, where necessary, amend or withdraw the authorisation by 31 March 2005 or by the date fixed for such an amendment or withdrawal in the respective Directive or Directives which added the relevant substance or substances to Annex I to Directive 91/414/EEC, whichever is the latest.

▼B

Article 4

This Directive shall enter into force on 1 October 2003.

Article 5

This Directive is addressed to the Member States.

▼B

ANNEX

In Annex I the following rows are added at the end of the table:

No	Common name, identification numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
‘59	Trifloxystrobin CAS No 141517-21-7 CIPAC No 617	Methyl (E)-methoxyimino-{(E)-a-[1-a-(a,a,a-trifluoro-m-tolyl)ethylideneaminooxyl]-o-tolyl}acetate	960 g/kg	1 October 2003	30 September 2013	Only use as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on trifloxystrobin, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied and/or monitoring programs may be initiated where appropriate.
60	Carfentrazone ethyl CAS No 128639-02.1 CIPAC No 587	Ethyl (RS)-2-chloro-3-[2-chloro-5-(4-difluoromethyl-4,5-dihydro-3-methyl-5oxo-1H 1,2,4-triazol-1-yl)-4-fluorophenyl]propionate	900 g/kg	1 October 2003	30 September 2013	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on carfentrazone-ethyl, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment: — Member States should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures should be applied where appropriate.
61	Mesotrione CAS No 104206-8 CIPAC No 625	2-(4-mesyl-2-nitrobenzoyl) cyclohexane-1,3-dione	920 g/kg The manufacturing impurity 1-cyano-6-(methylsulfonyl)-7-nitro-9H-xanthen-9-one is considered to be of toxicological concern and must	1 October 2003	30 September 2013	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on mesotrione, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account.

▼B

No	Common name, identification numbers	IUPAC Name	Purity (1)	Entry into force	Expiration of inclusion	Specific provisions
			remain below 0.0002 % (w/w) in the technical product.			
62	Fenamidone CAS No 161326-34-7 CIPAC No 650	(S)-5-methyl-2-methylthio-5-phenyl-3-phenylamino-3,5-dihydroimidazol-4-one	975 g/kg	1 October 2003	30 September 2013	Only use as fungicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on fenamidone, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment Member States: — should pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions, — should pay particular attention to the protection of non-target arthropods, — should pay particular attention to the protection of aquatic organisms. Risk mitigation measures should be applied where appropriate.
63	Isoxaflutole CAS No 141112-29-0 CIPAC No 575	5-cyclopropyl-4-(2-methylsulfonyl-4-trifluoromethylbenzoyl) isoxazole	950 g/kg	1 October 2003	30 September 2013	Only use as herbicide may be authorised. For the implementation of the uniform principles of Annex VI, the conclusions of the review report on isoxaflutole, and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 15 April 2003 shall be taken into account. In this overall assessment Member States: — must pay particular attention to the protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions. Risk mitigation measures or monitoring programs should be applied where appropriate.

(1) Further details on identity and specification of active substances are provided in the review report.'